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| APPLICATION NO. | | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-----------------------|------|-------------|----------------------|-------------------------|------------------|--|
| 09/886,327 | | 06/21/2001 | James Allen McEwen | 1077-023-PWH | 6889 | |
| 21034 | 7590 | 01/05/2004 | | EXAMI | EXAMINER | |
| IPSOLON | | | BUI, VY Q | | | |
| 805 SW BR PORTLANI | | • | | ART UNIT | PAPER NUMBER | |
| | , | | | 3731 | | |
| | | | | DATE MAILED: 01/05/2004 | ı | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| • | <u> </u> | | | ()> |
|--|--|--|--|------|
| - | | Application No. | Applicant(s) | |
| | _ | 09/886,327 | MCEWEN, JAMES ALLEN | |
| | Office Action Summary | Examiner | Art Unit | |
| | | Vy Q. Bui | 3731 | |
| Period f | The MAILING DATE of this communicator Reply | tion appears on the cover sheet | with the correspondence address | |
| THE - Extended after aft | MORTENED STATUTORY PERIOD FOR MAILING DATE OF THIS COMMUNICA ensions of time may be available under the provisions of 3 or SIX (6) MONTHS from the mailing date of this communication of the period for reply specified above is less than thirty (30) of the period for reply is specified above, the maximum statuture to reply within the set or extended period for reply will reply received by the Office later than three months after need patent term adjustment. See 37 CFR 1.704(b). | ATION. FOR 1.136(a). In no event, however, may cation. ays, a reply within the statutory minimum of the corp period will apply and will expire SIX (6) M. by statute, cause the application to become | a reply be timely filed nirty (30) days will be considered timely. DNTHS from the mailing date of this communication ABANDONED (35 U.S.C. § 133). | n. |
| 1)⊠ | Responsive to communication(s) filed | on <u>10 October 2003</u> . | | |
| 2a) <u></u> ☐ | This action is FINAL . 2b) | ∑ This action is non-final. | | |
| 3) | Since this application is in condition for closed in accordance with the practice | allowance except for formal ma under <i>Ex parte Quayle</i> , 1935 C | itters, prosecution as to the merits is D. 11, 453 O.G. 213. | 5 |
| Disposi | tion of Claims | | | |
| 4)🖂 | Claim(s) 1,2,5,6,8-13,15-17,19 and 20 | is/are pending in the application | ı. | |
| · | 4a) Of the above claim(s) is/are | | | |
| 5) | Claim(s) is/are allowed. | | | |
| 6)⊠ | Claim(s) 1,2,5,6,8-13,15-17,19 and 20 | is/are rejected. | | |
| , | Claim(s) is/are objected to. | | | |
| 8) | Claim(s) are subject to restriction | n and/or election requirement. | | |
| Applica | tion Papers | | | |
| 9)[| The specification is objected to by the E | Examiner. | | |
| 10) | The drawing(s) filed on is/are: a |) ☐ accepted or b) ☐ objected t | o by the Examiner. | |
| | Applicant may not request that any objection | | | |
| | Replacement drawing sheet(s) including th | | | d). |
| 11) | The oath or declaration is objected to b | y the Examiner. Note the attach | ed Office Action or form PTO-152. | |
| • | under 35 U.S.C. §§ 119 and 120 | | | |
| 12) <u></u> a | Acknowledgment is made of a claim for the control of the priority do not control of the certified copies of the certified copies of the certified copies of the priority do not control of the certified copies of the cer | ocuments have been received. ocuments have been received in the priority documents have been | Application No | |
| 13) <u> </u> | application from the Internationa See the attached detailed Office action of Acknowledgment is made of a claim for since a specific reference was included in 37 CFR 1.78. a) The translation of the foreign language. | Il Bureau (PCT Rule 17.2(a)). for a list of the certified copies not domestic priority under 35 U.S.6 in the first sentence of the specificage provisional application has | ot received. C. § 119(e) (to a provisional applicat ication or in an Application Data Sho been received. | eet. |
| 14)[_] | Acknowledgment is made of a claim for reference was included in the first senter | nce of the specification or in an | Application Data Sheet, 37 CFR 1.70 | 8. |
| Attachme | | F | | |
| 2) Not | ice of References Cited (PTO-892) ice of Draftsperson's Patent Drawing Review (PTC rmation Disclosure Statement(s) (PTO-1449) Papi | 0-948) 5) Notice of | v Summary (PTO-413) Paper No(s) f Informal Patent Application (PTO-152) | |

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 1. Claims 1, 5-6, 11, 13-15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over SMITH and NEPHEW RICHARDS' cuff (now is SAMMONS PRESTON ROLYAN, Bolingbrook, Illinois).

Regarding claims 1, 5-6, 11, 13-15 and 18, SMITH and NEPHEW RICHARDS, Inc., Memphis, Tennessee discloses a pair of a tourniquet cuff and a stockinette sleeve and inherently a method of using the pair of the tourniquet cuff and the stockinette sleeve. The pair comprises a tourniquet cuff having a length sufficient for encircling a limb having a limb circumference within a range of not less than a predetermined minimum (cuff overlap about four inches, first page, SMITH and NEPHEW RICHARDS)

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and not more than a predetermined maximum (cuff overlap about three inches, first page SMITH and NEPHEW RICHARDS), and wherein the cuff has a color code thereon that is indicative of that range (see list of color coding on third page, SMITH and NEPHEW RICHARDS' disposable cuffs), a stretchable protection sleeve/stockinette sleeve made of stockinette applied to the limb such that the sleeve circumference should be less than the limb's circumference to avoid any wrinkles in the stockinette sleeve (item 4, page 1, SMITH and NEPHEW RICHARDS), and instrument for pressurize the cuff. SMITH and NEPHEW RICHARDS discloses stockinette sleeve standard on each tourniquet (see third page, SMITH and NEPHEW RICHARDS' disposable cuffs). Inherently, there must be a means (such as a label, a mark, an alphabet code, a color code ...) to indicate a match between a cuff and an associated stockinette sleeve to help a physician to select a right pair of cuff and stockinette sleeve to use on a patient. Alternatively, it would have been obvious to one of ordinary skill in the art at the time the invention was made to mark or label a sleeve to match an associate cuff so as to help a physician or a user to identify the right pair of cuff and sleeve for a patient.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

⁽a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 8-10, 12 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over SMITH and NEPHEW RICHARDS, Inc. (now is SAMMONS PRESTON ROLYAN, Bolingbrook, Illinois).

As to claims 2, 12, SMITH and NEPHEW RICHARDS does not expressly disclose same color-coding for a pair of a cuff and an associate sleeve. However, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to mark both a cuff and an associate sleeve with the same color to help a user to identify and match quickly a separate cuff and its associate sleeve and avoid a use of a pair a cuff and a unmatched sleeve, which could render a tourniquet procedure less effective.

As to claim 17, SMITH and NEPHEW RICHARDS does not disclose a separate sealed package for a matching pair of a cuff and a sleeve. However, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to put a pair of a cuff and an associate sleeve in a package, such as a sealed plastic bag, so as to pre-select the right pair of a cuff and an associate sleeve for a user.

Regarding claims 8-10, SMITH and NEPHEW RICHARDS, Inc., Memphis,
Tennessee discloses substantially all limitations as recited in the claims except the
manner in which the sleeve is constructed to carry the color code thereon. It would
have been obvious to one of ordinary skill in the art at the time of the invention was
made to construct the sleeve as claimed for this is just one way to make the sleeve and
this construction would make no critical effect to the performance of the device.

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3. Claims 16, 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over SMITH and NEPHEW RICHARDS, Inc., Memphis, Tennessee.

Regarding claims 16, 19-20, SMITH and NEPHEW RICHARDS, Inc., Memphis, Tennessee does not disclose the stockinette sleeve applying a pressure less than a predetermined pressure of 2 mmHg on the limb or maximum pressure to be less than 25mmHg and other features as claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make experiments to determine the optimum value predetermined pressure of 2 mmHg to 25mmHg since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

As to claims 21-22, SMITH and NEPHEW RICHARDS, Inc., Memphis, Tennessee discloses substantially the claimed invention. The additional features as recited in the claims are well known. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to provide SMITH and NEPHEW RICHARDS, Inc., Memphis, Tennessee device with the additional features as claimed.

Response to Amendment

The amendment filed on 10/10/2003 under 37 CFR 1.131 has been considered but is ineffective to overcome the cited reference.

It would appear that the device of the reference qualifies for either anticipation 102 rejection or obviousness 103 rejection. The reference does not disclose any specific range of pressure inserted by a stockinet on a limb. However, the pressure exerted by the stockinet on a limb of a patient can be well within the pressure range as

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claimed. The Examiner is not certain that one can claim a novel method when the method has been used in real life, even though a user may do not accurately know a specific range of pressure when the stockinet is applied to a limb.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. SMITH et al (4,650,475) discloses same color coding of a cuff and a sleeve in a medical device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-2708 for regular communications and 703-308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

VQB

December 22, 2003